## REMARKS

Examiner's Conclusions Regarding Entitlement to Priority

Applicant respectfully disagrees with the Examiner's conclusions regarding entitlement of the present application to claims of priority made under 35 U.S.C. §§119(e) and 120. As the response provided below does not require resolution of the question of entitlement to priority, no further comments are being provided at this time. Applicant expressly reserves the right to further dispute, if necessary, the Examiner's assertions regarding the support for the present claims in one or more earlier-filed applications to which Applicant has claimed priority.

Claims

As recommended by the Examiner, claim 40 has been cancelled as being essentially duplicative of claim 39.

Rejection of Claims 33-37 Under 35 U.S.C. § 112, 1st Paragraph, Enablement

The Examiner has maintained the rejection of claims 33-37 "because the specification, while being enabled for claims limited in scope to a polypeptide of SEQ ID NO:2, and a polypeptide of SEQ ID NO:2 lacking is associated signal peptide, does not reasonably provide enablement for claims to various % variants of SEQ ID NO:2, which do not have a functional activity, or do not have the same functional activity as SEQ ID NO:2." According to the Examiner, "the issue is that the present claims encompass inactive polypeptides as there is no functional limitation associated with the claimed polypeptide variants, and the specification does not teach how to use those inactive variants of SEQ ID NO:2."

As an initial matter, Applicant notes that the mere possibility that a genus claim may encompasses "inoperative" species is not a proper basis for holding the claim to define an invention that is not enabled by the specification. However, to expedite examination, Applicant has amended the claims to add a functional limitation that addresses the Examiner's concerns regarding the question of coverage of the claims (i.e., to "inactive" variants). In view of this amendment, Applicant respectfully requests that the Examiner withdraw the rejection of claims 33-37 on the basis of §112, first paragraph (enablement).

Rejection of Claims 33-37 Under 35 U.S.C. § 112, 1st Paragraph, Written Description

The Examiner has maintained the rejection of claims 33 to 37 as "containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." The Examiner states that "the claims are drawn to a genus of polypeptides that is defined only by % sequence identity to a particular polypeptide sequence, and no particular conserved structure or other disclosed distinguishing feature is required."

Applicant submits that the amendments made by the present response to the claims address the Examiner's concerns and respectfully requests that the Examiner with draw the rejection of claims 33-37 on the basis of §112, first paragraph (written description).

Rejection of Claims 33-42 under 35 U.S.C. § 102(b) as Being Anticipated by Lal, *et al.*, WO 200000610-A2 ("Lal")

The Examiner asserts that "the statute of 102(b) itself merely requires that the invention was patented *or described* in" a prior art reference [emphasis in original]. The Examiner also states that the "the present invention is directed to a product, an isolated polypeptide, which sequence was *disclosed* in the [*Lal et al.*] prior art reference. As such the, the polypeptide of the present invention has been well *described* by the prior art reference, and the prior art reference meets the anticipating requirements of 102(b) [emphasis added]."

The Examiner's position appears to be that by merely *naming* a polypeptide sequence, and without providing any information regarding biological role, function or activity of the polypeptide that would enable one of skill to use the polypeptide sequence in any manner, *Lal et al.* anticipates the presently claimed polypeptides under 35 U.S.C. § 102(b). Applicant submits that this rejection is improper for several reasons, and respectfully requests the Examiner to withdraw this rejection.

*Applicant's observations on the scientific deficiencies of the Lal et al. disclosure have not been contested by the Examiner*

The Examiner has not contested Applicant's explanation of the scientific deficiencies of the *Lal et al.* disclosure, which are numerous. As previously explained, the majority of the Lal Disclosure is not specific to the relevant polypeptide sequence (SED ID NO:94) disclosed therein. *Lal et al.*, discloses a total of 134 human signal peptide-containing proteins (referred to in *Lal et al.*, and hereinafter as "HSPP") and their corresponding nucleotide sequences, but provides nothing more than generic (i.e., non-specific) recitations regarding the use of those polypeptide sequences. For example, *Lal et al.*, contains the following statements – none of which are specific to the polypeptide of SEQ ID NO: 94, but instead are cited to apply to all 134

sequences that are disclosed in the application – regarding *possible grounds* to support, for example, utility of the disclosed polypeptides:

- ...the expression of HSPP is closely associated with proliferative, cancerous, inflamed, cardiovascular, nervous, reproductive, hematopoietic/immune, and development tissue. Therefore, HSPP appears to play a role in cell proliferation disorders including cancer; inflammation; and cardiovascular, neurological, reproductive, and developmental disorders. Page 40, lines 10-15.

- In the treatment of cell proliferative disorders...associated with increased HSPP expression or activity, it is desirable to decrease the expression or activity of HSPP. Page 4, lines 15-18.

- In the treatment of ...conditions associated with decreased HSPP expression or activity, it is desirable to increase the expression or activity of HSPP. Lal goes on to list approximately 300 diseases or conditions that may possibly be treated by increasing HSPP expression or activity. Page 40, line 18 – page 43, line 6.

It appears that these predictions regarding the 134 HSSP polypeptides disclosed in *Lal et al.* are grounded merely on a tissue distribution analysis. However, that analysis fails to provide one of skill in the art any data that reasonably establishes—or that can be used to establish—any biological function for the disclosed HSSP sequences, let alone a biological function specific to SEQ ID NO:94.

In fact, the only information provided in *Lal et al.*, that specifically concerns SEQ ID NO:94 (and the nucleotide sequence that encodes it (SEQ ID NO:228)) in Tables 1, 2, and 3 is incorrect, as pointed out in the last response filed by Applicant on December 5, 2003. As pointed out then, the failed attempt by *Lal et al.*, to accurately describe or correctly predict the functions or activities of the polypeptide makes *Lal et al.*, incapable of providing a disclosure adequate to anticipate the presently claimed polypeptide.

As mentioned above, the Examiner has not contested these observations regarding the *scientific* deficiencies of the *Lal et al.* disclosure. Instead, the Examiner maintains that these deficiencies in *Lal et al.* do not affect its status as an anticipatory prior art reference under 35 U.S.C. §102(b). In particular, the Examiner merely cites the language of § 102(b) to maintain the rejection (that Lal et al. describes the polypeptide of the present invention). The Examiner

also apparently considers there to be no legal consequence of the failure of *Lal et al.* to disclose, for example, a "utility" for a claimed invention.

*Lal et al. is legally insufficient to anticipate the presented claims*

Applicant has maintained throughout the examination of this application that the scientifically deficient disclosure of *Lal et al.* renders it legally insufficient to anticipate the appealed claims. In particular, the *Lal et al.* disclosure does not provide an accurate or unequivocal characterization of any biological function, activity or role of the putative chemokine. Instead, it merely discloses a nucleotide and polypeptide sequence and speculates – inaccurately and incompletely – as to the diseases that may be implicated by the chemokine.

Applicant notes that, under the legal standards used to evaluate whether a printed publication is sufficient to constitute a bar to patenting under 35 U.S.C. 102(b), *Lal et al.*, is insufficient to be prior art to the presently claimed invention. To qualify as prior art, a printed publication must enable those skilled in the art to "understand the nature and operation of the invention and carry it into practical use." See, *In re LeGrice*, 301 F.2d 929, 936, 133 U.S.P.Q. 365 (C.C.P.A. 1962) ("The public purpose of section 102(b) is clear enough, and has been enunciated or assumed in the very considerable body of decisional law in which the clause 'described in a printed publication' has been interpreted with respect to whether the publication has in fact conveyed such knowledge of an invention to the public as to put the public in possession of the invention."). If a printed publication fails to enable one skilled in the art to carry an invention into practical use (e.g., because it fails to adequately describe or it fails to teach how to use the subject matter), it cannot be a bar to patenting under 35 U.S.C. §102(b). And, it is well established that a disclosure that fails to set forth a specific, substantial or credible utility, by definition, means that the disclosure cannot teach a person of ordinary skill how to use the subject matter. See, *In re Brana*, 51 F3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995).

Under the standards articulated for sufficiency of disclosure of a printed publication under 35 U.S.C. §102(b), then, the *Lal et al.* disclosure is insufficient to be prior art to the presently claimed invention.

Rejection of Claim 43 under 35 U.S.C. § 103(a) as being obvious over *Lal et al.*, in view of U.S. Patent No. 5,116,964 (Capon)

The Examiner maintains his rejection of Claim 43 over *Lal et al.*, in view of *Capon et al.* for the reasons provided in the previous Office Action, paper No. 13.

For the reasons presented above, Applicant maintains that *Lal et al.*, is not prior art under 35 U.S.C. § 102(b) to the present claims. As such, Applicant believes a rejection under 35 U.S.C. 103(a) of claim 43 in view of Lal et al., alone or in view of any other reference, is inappropriate.

Additional Comments

In view of this amendment and response, Applicant submits that the present application is in condition for allowance and should be passed to issue. If the Examiner believes that the application is not in condition for allowance or cannot be passed to issue in view of this response, Applicant respectfully requests that the Examiner contact the undersigned prior to taking any further action in this application.

Respectfully submitted,
for GENENTECH, INC.

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